UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,296	07/15/2008	Wolfgang-Michael Franz	0286220151	4483

22428 7590 12/21/2010

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
12/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,296	FRANZ ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8 and 15-24* is/are pending in the application.

4a) Of the above claim(s) *3 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5,6,8 and 15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/06, 7/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants election, with traverse, of species: (1) administration of G-CSF after surgical or interventional procedure; and (2) myocardial infarction (claims 2-, 5-6, 8, 15-24), in the reply filed on 10/4/2010 is acknowledged. The traversal is on the ground(s) that the restriction is improper and it would not be unduly burdensome for the Examiner to search all the listed species in the claims. Furthermore, Applicants assert that the invention is drawn to "treating organ dysfunction caused by ischemia comprising administering an effective amount of G-CSF", accordingly, the Examiner must search G- CSF as a treatment, this search will necessarily encompass treatments that occur before, after and during the surgical or interventional procedure and thus, there would be no undue burden on the Examiner to review treatment before, after or during the surgical or interventional procedure. Additionally, Applicants argue that there would be no undue burden for the Examiner to search and examine the species of ischemia. However, contrary to Applicants argument, an election of species has been made by the Examiner as a starting point for search. Once the elected species is determined to be allowable, the Examiner will search the next species. Therefore, Applicants arguments are unpersuasive with respect to the election of species requirements.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-4 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Amended claims 2, 5-6, 8 and 23-24 (11/4/2010) and original claims 15-22 are under consideration by the Examiner.

Claim Rejections - 35 USC § 112, second paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5-6, 8, 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite for several reasons.

Claim 2, is unclear because it recites the acronym "G-CSF" without first defining what it represents in the independent claim. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym. Appropriate correction is required.

Claim 2, lines 3-4, is vague and indefinite because it recites "a surgical or interventional procedure". The metes and bounds of this term are unclear. It is unclear whether the surgical procedure is a coronary procedure or a procedure to any of the other organs in the patient's body. It is suggested that the limitations of claim 16 be recited in independent claim 2 to obviate this rejection.

Claim 2, line 5, is vague and indefinite because the claim recites "organ function". The metes and bounds of the term are unclear. Which organ is being referred to in the claim. It is

suggested that the claim be amended to recite the specific organ for which there is a basis in the instant specification, i.e. heart.

Claim 2 is also vague and indefinite because it unclear when during the treatment G-CSF is to be administered to the patient.

Claim 5 is vague and indefinite because it is unclear how long after the surgical procedure, the G-CSF is to be administered to the patient. It is suggested that the limitations of claim 6 be recited in claim 5 to obviate this rejection.

Claim 8, line 3, is vague and indefinite because it recites "trauma and/or surgical procedures". It is unclear what the metes and bounds of this term are. It is suggested that to obviate this rejection, the claim be amended to recite the specific "trauma and/or surgical procedures" for which there is a basis in the instant specification.

Claim 15, line 2, is vague and indefinite because it recites "organ defects". It is suggested that the claim be amended to recite the specific organ that is encompassed by the claim, i.e. heart. Furthermore, the metes and bounds of the term "defects" is unclear. Does the term encompass a hole in the heart, perforation of a vessel, ventricular remodeling or a deviated septum. It is suggested that to obviate this rejection, the claim be amended to recite the specific defects for which there is a basis in the instant specification.

Claim 17, line 3, is vague and indefinite because it recites "recruiting stem and/or progenitor cells". It is unclear what the metes and bounds of this term are. It is suggested that to obviate this rejection, the claim be amended to recite the specific "recruiting stem and/or progenitor cells".

Claims 6, 16, 18-24, are rejected as vague and indefinite insofar as they depend upon the above rejected claims for their limitations.

Claim rejections-35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3a. Claims 2, 8, 15, 17-24, are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 01/94420.

WO 01/94420 teaches treating myocardial infarction in a patient by administering G-CSF (see abstract; page 8, lines 23-24; pages 21-22; Figure 1). The reference also discloses that the G-CSF mobilizes CD34+ cells (Figure 1, page 21).

The reference teaches administering G-CSF and obtaining a beneficial outcome in treatment of myocardial infarction (see abstract). With respect to the instant claims, it would an inherent property of the prior art method to recruit the stem and progenitor cells recited in instant claims 17-22. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP. 2112-2112.02. See Bristol-Myers

Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001) in which the Court found that preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

While the prior disclosure is silent as to the recruitment of the type of cells to the heart by the administration of G-CSF, the instant claims merely recite a newly discovered result, i.e., a known method to the same use of G-CSF. The claimed process is not directed to a new use, it is the same use and it consists of the same method as described by the reference.

The WO 01/94420 reference teaches the administration of G-CSF in a method of treating myocardial infarction. Therefore, the method disclosed in the reference meets the limitations recited in claims 2, 8, 15, 17-24.

3b. Claims 2, 8, 15, 17-24, are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 02/099081.

The reference teaches treating myocardial infarction in a patient by administering G-CSF (see abstract; page 4, lines 30-32; page 5, lines 1-8; page 6, lines 19-27). The reference also discloses that the G-CSF mobilizes progenitor cells (pages 17-22).

The reference teaches administering G-CSF and obtaining a beneficial outcome in treatment of myocardial infarction (see abstract). With respect to the instant claims, it would an inherent property of the prior art method to recruit the stem and progenitor cells recited in instant

claims 17-22. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP. 2112-2112.02. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001) in which the Court found that preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

While the prior disclosure is silent as to the recruitment of the type of cells to the heart by the administration of G-CSF, the instant claims merely recite a newly discovered result, i.e., a known method to the same use of G-CSF. The claimed process is not directed to a new use, it is the same use and it consists of the same method as described by the reference.

The WO 02/099081 reference teaches the administration of G-CSF in a method of treating myocardial infarction. Therefore, the method disclosed in the reference meets the limitations recited in claims 2, 8, 15, 17-24.

3c. Claims 2, 8, 15, 17-24, are rejected under 35 U.S.C. § 102(e) as being anticipated by US 2003/147862.

The reference teaches treating myocardial infarction in a patient by administering G-CSF (see abstract; [0019], [0020], [0021]; claims 2-4).

The reference teaches administering G-CSF and obtaining a beneficial outcome in treatment of myocardial infarction. With respect to the instant claims, it would an inherent

property of the prior art method to recruit the stem and progenitor cells recited in instant claims 17-22. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP. 2112-2112.02. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001) in which the Court found that preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

While the prior disclosure is silent as to the recruitment of the type of cells to the heart by the administration of G-CSF, the instant claims merely recite a newly discovered result, i.e., a known method to the same use of G-CSF. The claimed process is not directed to a new use, it is the same use and it consists of the same method as described by the reference.

The reference teaches the administration of G-CSF in a method of treating myocardial infarction. Therefore, the method disclosed in the reference meets the limitations recited in claims 2, 8, 15, 17-24.

3d. Claims 2, 8, 15, 17-24, are rejected under 35 U.S.C. § 102(e) as being anticipated by EP 1 327 449 A.

The reference teaches treating ischemic heart disease, including myocardial infarction, in a patient by administering G-CSF (see abstract; page 5, [0024]; page 6, [0031]).

The reference teaches administering G-CSF and obtaining a beneficial outcome in treatment of myocardial infarction. With respect to the instant claims, it would an inherent property of the prior art method to recruit the stem and progenitor cells recited in instant claims 17-22. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP. 2112-2112.02. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001) in which the Court found that preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

While the prior disclosure is silent as to the recruitment of the type of cells to the heart by the administration of G-CSF, the instant claims merely recite a newly discovered result, i.e., a known method to the same use of G-CSF. The claimed process is not directed to a new use, it is the same use and it consists of the same method as described by the reference.

The reference teaches the administration of G-CSF in a method of treating myocardial infarction. Therefore, the method disclosed in the reference meets the limitations recited in claims 2, 8, 15, 17-24.

Conclusion

No claim is allowed.

Claims 2, 5-6, 8, and 15-24 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Prema Mertz, Ph.D., J.D.
Primary Examiner
Art Unit 1646